

REMARKS

The present Amendment is submitted to supplement the Amendment filed by Certificate of Mailing on August 21, 2002 and respond to the Official Action dated February 21, 2002. Claims 1 and 30 are amended to more clearly recite that the first and second polymer components are effective for providing controlled sustained release of the pharmaceutically active substance from the composition for up to at least 20 hours as set forth in the specification at page 10, lines 14-15. A Version With Markings Showing Changes Made is attached. Claims 31-34 are added, support for claims 31 and 32 being found in original claim 27 and support for claims 33 and 34 being found in original claims 1-29.

For the reasons set forth in detail in the remarks portion of the Amendment filed by certificate of mail on August 21, 2002, Applicants submit that the Examiner has not established a prima facie case of obviousness with respect to the presently claimed compositions, whereby the rejection under 35 U.S.C. §103 has been overcome. Reconsideration is respectfully requested.

Respectfully submitted,



Holly D. Kozlowski, Reg. No. 30,468
Attorney for Applicants
1900 Chemed Center
255 East Fifth Street
Cincinnati, Ohio 45202
Tel: (513) 977-8568
Fax: (513) 977-8141

VERSION WITH MARKINGS SHOWING CHANGES MADE

1. (Fourth Amendment) A controlled release pharmaceutical composition comprising:

- (a) at least one pharmaceutically active substance having a water contact angle (θ) such that $\cos \theta$ is between +0.9848 and -0.9848;
- (b) a first intelligent polymer component; and
- (c) a second intelligent polymer component having opposite wettability characteristics to said first intelligent polymer component, said second intelligent polymer component comprising hydroxyethylcellulose or a mixture of hydroxyethylcellulose and hydroxypropyl methyl cellulose, the first and second polymer components being present in a ratio in the range of about 1:100 to about 100:1 by weight,

wherein said first and second polymer components are effective for providing controlled sustained release of said pharmaceutically active substance from said composition for up to at least 20 hours.

30. (Third Amendment) A controlled release pharmaceutical composition comprising:

- (a) at least one pharmaceutically active substance having a water contact angle (θ) such that $\cos \theta$ is between +0.9848 and -0.9848;
- (b) a first intelligent polymer component comprising ethylcellulose
- (c) a second intelligent polymer component having opposite wettability characteristics to said first intelligent polymer component, said second intelligent polymer component comprising hydroxyethylcellulose, or hydroxypropyl methyl cellulose, or a mixture of hydroxyethylcellulose and hydroxypropyl methyl cellulose, the first and second polymer components being present in a ratio in the range of about 1:100 to about 100:1 by weight, wherein said first and second polymer components are effective for providing

controlled sustained release of said pharmaceutically active substance from said composition for up to at least 20 hours; and

wherein components (a), (b) and (c) are formulated as a homogeneous matrix and said composition has a moisture content of less than 3%.

823529v1
10914-11